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52

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/639,945

Applicant(s)

GELLMAN ET AL.

Examiner

Charles A. Marmor, II

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 29-34 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because:
 - a. In Figure 2B, reference character “31” apparently should read --32--.
 - b. In Figure 2D, reference character “31” apparently should read --32--.
 - c. In Figure 5B, reference characters “230” and “240” appear to be reversed at the distal end of the drawing with respect to the proximal end of the drawing. Therefore, reference character “230” (two lowermost occurrences) apparently should read --240-- and reference character “240” (lowermost occurrence) apparently should read --230--.
 - d. In Figure 5C, reference characters “230” and “240” appear to be reversed with respect to Figure 5A. Therefore, reference character “230” (both occurrences) apparently should read --240-- and reference character “240” apparently should read --230--.
 - e. In Figure 7B, reference characters “410” and “412” apparently should be aligned with the magnet having the positive (+) pole closest to the exterior of the stylet in order to be consistent with the disclosure of the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must

Art Unit: 3736

be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "8" as included in Fig. 1, "275" as included in Fig. 5B, "45" as included in Fig. 6, and "51" as included in Fig. 6. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Art Unit: 3736

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “32” as mentioned at page 5, line 29 and page 6, line 4; “400” as mentioned at page 11, line 1; and “300” as mentioned at page 11, line 29. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled “Replacement Sheet” in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:
- a. At page 2, line 23, it is unclear how the “second ext opening” can be located adjacent to itself.
 - b. At page 4, line 8, “C-C of FIG. 2B” apparently should read --D-D of FIG. 2C--. There is no “C-C” illustrated in FIG. 2B.
 - c. At page 6, line 11, “31” apparently should read --33--.
 - d. At page 6, line 12, “31” apparently should read --33--.
 - e. At page 6, line 13, “31” apparently should read --33--.
 - f. At page 8, line 7, --be-- apparently should be inserted before “urged”.

Art Unit: 3736

- g. At page 9, line 25, "240" apparently should read --230--.
- h. At page 9, line 29, "230" apparently should read --240--.
- i. At page 9, line 30, "230" apparently should read --240--.
- j. At page 10, line 9, "240" (both occurrences) apparently should read --230--.
- k. At page 10, line 10, "240" apparently should read --230--.
- l. At page 11, line 11, "410, 410'" apparently should read --412, 412'--.

Appropriate correction is required.

Claim Objections

5. Claim 8 is objected to because of the following informalities: in line 1, "the distal" apparently should read --a distal--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6, 7, 13-18 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "said supply of markers" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no supply of markers recited in claims 1, 2 or 6 prior to this recitation. This limitation is also recited in line 1 of claim 7.

Art Unit: 3736

Regarding claim 13, the claim language renders the claim indefinite. It is unclear how the "second exit opening" can be located adjacent to itself.

Regarding claim 14, the claim language renders the claim indefinite. In view of the limitation "the exit opening" recited in line 1, it is unclear whether the system includes only one exit opening or if there can be more than one exit opening as suggested by the language of claim 12.

Regarding claim 15, the claim language renders the claim indefinite. It is unclear whether the limitation "the exit opening" recited in line 1 is intended to refer to the first exit opening or the second exit opening.

Claim 16 recites the limitation "the controller" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no controller recited in the claims prior to this recitation.

Claim 17 recites the limitation "the handle portion" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no handle portion recited in claims 1 or 17 prior to this recitation.

Claim 32 recites the limitation "the multiple tissue samples" in line 2. There is insufficient antecedent basis for this limitation in the claim. There are no tissue samples recited in the claims prior to this recitation.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-5, 8-15, 19-23, 25 and 29-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Burney et al. ('700). Burney et al. teach a biopsy marker assembly (10, 200) including a sampling portion locatable inside the body and including a stylet (14, 214) having a side-notch sampling region (16, 216) and a cannula (12, 212). The stylet and cannula are relatively moveable along the stylet axis to position the cannula over the sampling region. A sample marker (20, 220) is locatable in and releasable from the sampling portion between the stylet and the cannula. The assembly may include a supply of multiple markers arranged sequentially and generally parallel to the stylet in a lumen communicating with chamber (219) (column 10, lines 15-20). A marker exit opening (16, 219) is disposed adjacent the distal end of the stylet and may be located proximal to, distal to, radially opposed to, or coincident with the side notch in the stylet (column 10, lines 2-14). The opening is oriented to eject a marker substantially parallel to the stylet. The exit opening may be formed by the open distal end of the cannula. Regarding claim 13, the marker exit opening (16, 219) located adjacent to either a proximal or distal axial periphery of the sampling side notch may be considered a first exit opening, and the open distal end of the cannula which may be locatable adjacent to the first exit opening may be considered a second exit opening. The marker (20, 220) is an elongated element indicative of the axial length of a tissue region from which a sample is taken. The elongated

Art Unit: 3736

element includes regions along its length distinguishable by MRI, ultrasound or fluoroscopy that may be spaced to indicate the length of a tissue region from which a sample is taken (column 6, lines 29-40). The marker may be at least partially biodegradable (column 6, lines 43-48). The marker includes a tissue engaging edge that resists proximal motion of the marker when the marker is in contact with the tissue (Figures 8, 15, 19 and 25). In operation, the stylet is inserted into a tissue mass, relative motion is caused between the stylet and the cannula to locate the cannula over the sampling region, and the marker is delivered from the sampling portion into the tissue while removing the stylet from the tissue. The process may be repeated when multiple markers are used. The markers may be correlated with the location of the sampled tissue, the samples may be analyzed for abnormal conditions, and the tissue may be treated (column 1, lines 13-20).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. ('700) in view of Dowlatshahi ('366). Burney et al., as discussed hereinabove, teach all of the limitations of the claims except that the system includes a control handle portion having a supply of markers and a marker pusher. Dowlatshahi teaches a biopsy site marking device having a control handle portion (50) housing a supply of markers (10) and a marker pusher (60) that is

Art Unit: 3736

actuated at the handle portion to selectively locate markers in a sampling portion of a cannula (20). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of Burney et al. with a control handle having a supply of markers and a marker pusher similar to that of Dowlatshahi in order to conveniently and compactly dispense a plurality of marker elements into a tissue mass of interest at a distal end of a cannula of a biopsy system.

12. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. ('700) in view of Sirimanne et al. ('437). Burney et al., as discussed hereinabove, teach all of the limitations of the claims except that the markers are distinguishable from other markers when viewed by MRI, ultrasound or fluoroscopy. Sirimanne et al. teach that it is advantageous to provide markers with a distinguishing or identifying mark (170) that enables a given marker to be distinguished from other markers using noninvasive imaging techniques in order to differentiate between multiple biopsy sites (paragraph [0059]). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide markers similar to those of Burney et al. with an identifying mark in light of the teachings of Sirimanne et al. so that a given marker may be distinguished from other markers using noninvasive imaging techniques in order to differentiate between multiple biopsy sites.

13. Claim 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. ('700) in view of Sinanan et al. ('715). Burney et al., as discussed hereinabove, teach all of the limitations of the claims except that the marker is magnetically fixed to the exterior of the

Art Unit: 3736

stylet. Sinanan et al. teach an anatomical marker that is magnetically attached to an introducer stylet in order to prevent premature deployment or shifting of the marker until the marker is securely affixed to a desired tissue area within the body. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to magnetically fix the marker to the stylet of Burney et al. in light of the teachings of Sinanan et al. so that the marker may not shift or be prematurely deployed from the stylet as the marker is axially translated upon advancement of the stylet and cannula and released into tissue upon retraction of the cannula to expose the stylet and marker.

Allowable Subject Matter

14. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 6 and 7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 6 and 7, no prior art of record teach or fairly suggest a needle biopsy system, as claimed by Applicant, including a supply of markers provided radially around a stylet such that the supply of markers is rotatable relative to the stylet axis.

Art Unit: 3736

Regarding claim 28, no prior art of record teach or fairly suggest a needle biopsy system, as claimed by Applicant, where a marker is magnetically fixed to the exterior of the stylet and the marker is translated by axial motion of the cannula to a location where it is magnetically repulsed from the cannula.

Conclusion

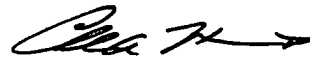
17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Voegele et al. ('248) teach a method for implanting a biopsy marker at a biopsy site. Foerster et al. ('055) teach devices for marking and defining particular locations in body tissue. Barsch ('177) teaches apparatus and methods for deploying an expandable biopsy marker.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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December 1, 2004